

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION**

Robert Blankenship,

Plaintiffs,

v.

Pfizer, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; David Rohling; Kmart of Michigan, Inc.; Art Redding; Kelli Strange; "A", that person, corporation or other legal entity who designed, manufactured, sold, distributed and failed to warn of the potential complications associated with the use of the drug Mirapex; "B", that person, corporation or other legal entity who failed to provide adequate warnings with respect to the complications associated with the use of the drug Mirapex; "C", that person, corporation or other legal entity who provided information to treating physician or Robert Blankenship; "D" that person, corporation or other legal entity who failed to adequately warn Mr. Blankenship's treating physician of the complications associated with the use of the drug Mirapex; "E", that person, corporation or other legal entity who filled the prescription for Robert Blankenship for the drug Mirapex and failed to warn of the complications associated with use of the drug; "F", that person, corporation or other legal entity who's negligence, wantonness or other wrongful conduct combined with the negligence, wantonness or other wrongful conduct of other defendants to cause the damages alleged herein, all of said fictitious defendants are unknown to Plaintiff at this time but will be substituted by amendment when ascertained,

CIVIL ACTION NO.

2:06-cv-0648-VPM

Defendants.

ANSWER AND REQUEST FOR JURY TRIAL

Defendant Pfizer Inc. (incorrectly identified as “Pfizer, Inc.”), by its undersigned counsel, hereby answers plaintiff’s Complaint in the above-captioned action (“the Complaint”) and asserts its affirmative and other defenses as follows:

STATEMENT OF THE PARTIES

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, and therefore denies the same.

2. Defendant admits that it is a U.S. corporation with its principal place of business located in New York, New York and is authorized to do business in Alabama. Defendant denies the remaining allegations of paragraph 2.

3. The allegations in Paragraph 3 are not directed to Defendant and, therefore, no response is required.

4. The allegations in Paragraph 4 are not directed to Defendant and, therefore, no response is required.

5. The allegations in Paragraph 5 are not directed to Defendant and, therefore, no response is required.

6. The allegations in Paragraph 6 are not directed to Defendant and, therefore, no response is required.

7. The allegations in Paragraph 7 are not directed to Defendant and, therefore, no response is required.

8. The allegations in Paragraph 8 are not directed to Defendant and, therefore, no response is required.

9. The allegations in Paragraph 9 are not directed to Defendant and, therefore, no response is required.

10. The allegations in Paragraph 10 are not directed to Defendant and, therefore, no response is required.

11. The allegations in Paragraph 11 are not directed to Defendant and, therefore, no response is required.

12. The allegations in Paragraph 12 are not directed to Defendant and, therefore, no response is required.

13. The allegations in Paragraph 13 are not directed to Defendant and, therefore, no response is required.

STATEMENT OF THE FACTS

14. Defendant is without knowledge or information to form a belief as to the truth of the allegations in paragraph 14, and therefore denies the same.

15. Defendant admits that Mirapex is the trade name for pramipexole dihydrochloride. Defendant admits that Mirapex is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's Disease. Defendant denies the remaining allegations in paragraph 15.

16. Defendant denies the allegations in paragraph 16.

17. Defendant admits that Mirapex belongs to the class of medications known as dopamine agonists. Defendant admits that Parkinson's Disease is a

chronic progressive neurological disease, and further states that the medical symptoms, conditions or treatment of the disease have been described in the peer reviewed medical literature. Defendant admits Mirapex binds with certain dopamine receptors. Defendant denies the remaining allegations in paragraph 17.

18. Defendant denies the allegations in paragraph 18.

19. Defendant denies the allegations in paragraph 19.

20. Defendant denies the allegations in paragraph 20.

21. Defendant denies the allegations in paragraph 21

22. Defendant denies the allegations in paragraph 22.

23. Defendant denies the allegations in paragraph 23.

24. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 regarding Mr. Blankenship's prescribing physicians. Defendant denies the remaining allegations in paragraph 24.

25. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 regarding Mr. Blankenship's wealth and gambling history, and therefore denies same.

26. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 regarding Mr. Blankenship's gambling, and therefore denies same.

COUNT ONE

(Alabama Extended Manufacturer's Liability Doctrine [AEMLD])

27. Defendant incorporates its responses to paragraphs 1-26 of the Complaint as if fully set forth herein.

28. Defendant denies the allegations in paragraph 28, except admits that it jointly promoted and marketed Mirapex with BIPI in the United States from July 1997 until May 2005 and manufactured Mirapex for BIPI.

29. Defendant denies the allegations in paragraph 29.

30. Defendant denies the allegations in paragraph 30.

31. Defendant denies the allegations in paragraph 31.

32. Defendant denies the allegations in paragraph 32.

COUNT TWO

(Negligence)

33. Defendant incorporates its responses to paragraphs 1-32 of the Complaint as if fully set forth herein

34. Defendant denies the allegations in paragraph 34.

35. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 35 regarding Defendant Rohling, and therefore denies same.

36. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 regarding Defendants Kmart, Redding and Strange, and therefore denies same.

37. Defendant denies the allegations in paragraph 37.

COUNT THREE

(Wantonness)

38. Defendant incorporates its responses to paragraphs 1-37 of the Complaint as if fully set forth herein

39. Defendant denies the allegations in paragraph 39.

40. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40 regarding Defendant Rohling, and therefore denies same.

41. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 regarding Defendants Kmart, Redding and Strange, and therefore denies same.

42. Defendant denies the allegations in paragraph 42.

COUNT FOUR

(Fraud)

43. Defendant incorporates its responses to paragraphs 1-42 of the Complaint as if fully set forth herein

44. Defendant denies making any misrepresentations and otherwise denies the allegations in paragraph 44.

45. Defendant denies the allegations in paragraph 45, except it admits it had, at various times, duties related to Mirapex pursuant to a regulatory scheme established by the United States Food and Drug Administration (“FDA”).

46. Defendant denies making any misrepresentations and otherwise denies the allegations in paragraph 46.

47. Defendant denies making any misrepresentations and otherwise denies the allegations in paragraph 47.

48. Defendant denies making any misrepresentations and otherwise denies the allegations in paragraph 48.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in the Complaint that have not previously been specifically admitted, denied or explained.

AFFIRMATIVE AND OTHER DEFENSES

Without assuming the burden of proof of such defenses that it would not otherwise have, in further response to the Complaint, Defendant pleads the following affirmative and other defenses:

1. The Complaint fails to state a claim against Defendant upon which relief can be granted.

2. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex is comprehensively regulated by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and plaintiff’s claims conflict with the FDCA,

with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with the specific determinations by the FDA specifying the language that should be used in the labeling accompanying the products. Accordingly, plaintiff's claims are preempted by the Supremacy Clause of the Constitution of the United States, Article VI, clause 2, and the laws of the United States, including but not limited to the FDCA and the regulations promulgated thereunder. Alternatively, Defendant is entitled to a presumption based on the FDA's approval of Mirapex that the product is not defective or unreasonably dangerous.

3. The conduct of Defendant in all activities with respect to Mirapex has been and is under the supervision of the FDA and its Division of Drug Marketing, Advertising and Communications, which are charged with regulating prescription drug product labeling, advertising and promotions. Thus, this action is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

4. The claims asserted in the Complaint are barred, in whole or in part, by the doctrine of abstention, in that the common law gives deference to discretionary actions by the FDA under the FDCA.

5. Plaintiff's injuries and damages, if any, may be due to idiosyncratic reactions to Mirapex for which Defendant cannot be held responsible.

6. The claims set forth in the Complaint are barred because plaintiff's alleged injuries and damages, if any, may have been actually or proximately caused or contributed to be caused by an act, omission of fault or by an intervening or superseding act of some person, entity or third party other than Defendant and/or for whom Defendant is not legally responsible.

7. The claims set forth in the Complaint are barred because the alleged injuries and damages, if any, may have been caused by medical conditions, disease, illness or processes (whether pre-existing or contemporaneous) unrelated to Mirapex.

8. The methods, standards, and techniques utilized with respect to the manufacture, testing, design, and marketing of Mirapex, if any, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the generally recognized, reasonably available and reliable state of the knowledge at the time the product was designed, tested, manufactured, and marketed.

9. The claims set forth in the Complaint are barred because the foreseeable therapeutic benefits of Mirapex outweighed any foreseeable risks of harm.

10. The claims set forth in the Complaint are barred under the doctrine of estoppel, waiver, ratification, laches, unclean hands and by the applicable statutes of limitations and/or repose and other related doctrines and principles or any one of them, and by plaintiff's inequitable conduct, lack of diligence, delay and inattention in pursuing such claims.

11. The claims set forth in the Complaint may be barred by the doctrine of informed consent and assumption of risks because plaintiff may have knowingly and voluntarily assumed the risk of injury.

12. To the extent applicable, Defendant is entitled to contribution from any person and/or entity whose negligence or other fault contributed to plaintiff's alleged injuries and damages.

13. To the extent plaintiff obtains recovery in any other case predicated on the same factual allegations, plaintiff is barred from seeking recovery against Defendant based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

14. The acts of Defendant alleged in the Complaint were not the direct and proximate cause of any injury or damage to plaintiff.

15. The claims asserted in the Complaint are barred, in whole or in part, because plaintiff lacks an adequate scientific basis to demonstrate any resulting harm or increased risk of future harm as a result of plaintiff's alleged Mirapex use.

16. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was marketed with adequate and sufficient warnings.

17. To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the Constitution of the United States and analogous provisions of the applicable state constitution.

18. Plaintiff's claims for damages may be barred, in whole or in part: (1) because plaintiff failed to mitigate any damages, and such failure to mitigate damages should proportionately reduce plaintiff's recovery and the allocation of any fault, if any exists, attributable to Defendant; (2) because plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) because the damages sought are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages;

(4) because plaintiff has failed to identify any purported injuries or damages with sufficient particularity; and (5) the Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive damages.

19. To the extent punitive damages are sought, plaintiff's punitive damages claims against Defendant: (1) have no basis in law or fact; (2) cannot be sustained in that the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Defendant; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Defendant prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Defendant's due process rights guaranteed by the Fifth, Eighth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by applicable state laws or other comparable laws would violate Defendant's due process and equal protection rights guaranteed by the Fifth, Eighth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Defendant for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Defendant's medicines would constitute impermissible multiple punishments for the same wrong, in violation of Defendant's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of

any applicable states' laws; and (6) cannot be sustained because any award of punitive damages, which are penal in nature, without according Defendant the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the right to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Defendant's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

20. To the extent punitive damages are sought, plaintiff's claims for punitive damages against Defendant cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Defendant; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would

violate Defendant's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

21. Plaintiff's demand for punitive damages is barred because Mirapex and its labeling were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

22. To the extent plaintiff makes a claim for punitive damages, Defendant asserts that plaintiff has not complied with statutory requirements to recover punitive damages.

23. To the extent punitive damages are sought, Defendant specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards that arose in the decisions of *BMW of North America Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group*, 532 U.S. 424 (2001); and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 123 S. Ct. 1513 (2003).

24. Defendant affirmatively pleads that any punitive damages that plaintiff may recover in this case should be capped in keeping with Alabama Code § 6-11-21 (1975), as amended in 1999 (Act. No. 99-358) and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999); see also *Horton Homes, Inc. v. Brooks*, 832 So. 2d 44 (Ala. 2001). Defendant adopts by reference the defenses, criteria, limitations, and standards mandated by this Alabama statute. The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States and the State of

Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

25. Defendant avers that any punitive damages award is subject to limitation based on harm that has occurred and harm that is likely to occur. *See TXO Prod. Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711 (1993).

26. Defendant avers that the method of imposing punitive damages violates Amendment 328, Section 6.11 of the Constitution of Alabama, which prohibits the use of a procedural rule to abridge, enlarge, or modify the substantive right of any party. *See Leonard v. Terminix Int'l Co.*, 854 So. 2d 529 (Ala. 2002).

27. The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

28. Defendant adopts the terms of any applicable legislative act or Alabama Supreme Court decision which now or hereafter precludes punitive damages or limits the amount of punitive damages that can be recovered in an action at law in Alabama.

29. Plaintiff may not be the real party in interest who has the right to prosecute these claims.

30. Plaintiff's claims are barred, in whole or in part, because Defendant did not make any false, misleading, or deceptive statements to plaintiff in its advertisements and/or promotional materials concerning Mirapex. As to any statement asserted against Defendant that plaintiff alleges to be false, misleading, or deceptive, Defendant had no reasonable grounds to believe, and did not believe

at the time such a statement was made, that the statement was false, misleading, or deceptive.

31. Plaintiff's claims may be barred, in whole or in part, due to lack of standing.

32. Plaintiff's claims may be barred, in whole or in part, due to failure to join indispensable parties and/or bring claims against the real party in interest.

33. Plaintiff's claims as set forth in the Complaint may be barred to the extent plaintiff misused or abused Mirapex, failed to use Mirapex properly, and/or used Mirapex negligently or used Mirapex in any other way except that for which it was intended.

34. To the extent applicable, Defendant specifically asserts the defense of contributory negligence.

35. Plaintiff's alleged injuries and damages, if any, were the result of independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Defendant or plaintiff's alleged ingestion of Mirapex.

36. Plaintiff's claims are barred pursuant to the Learned Intermediary Doctrine.

37. Plaintiff's claims against Defendant are barred under Section 402A, comments j and k of the Restatement (Second) of Torts and Sections 4 and 6 of the Restatement (Third) of Torts: Products Liability.

38. Should Defendant be held liable to plaintiff, which liability is specifically denied, Defendant would be entitled to a set-off for all sums of money

received or available from or on behalf of any tortfeasors for the same injuries alleged in the Complaint.

39. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any regulatory body with jurisdiction over the product, including but not limited to the United States, any state, and any agency thereof.

40. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex was designed, tested, manufactured, and labeled in accordance with state-of-the-art and industry standards existing at the time of sale.

41. Notwithstanding plaintiff's claims and contentions, plaintiff received all or substantially all of the benefit of Mirapex that he had intended to receive, and to that extent any damages and/or restitution that plaintiff might be entitled to recover from Defendant must be correspondingly reduced.

42. Venue in this district and/or division may be improper and/or inconvenient.

43. To the extent that plaintiff is alleging fraud or similar conduct, plaintiff has failed to plead fraud with sufficient particularity.

44. Plaintiff's claims are barred, in whole or in part, by the Alabama Product Liability Act, ALA. CODE §§ 6-5-500 to 6-5-525.

45. Any verdict or judgment rendered against Defendant must be reduced under federal law and/or the laws of the State of Alabama by those amounts which

have been, or will, with reasonable certainty, replace or indemnify plaintiff, in whole or in part, for any past or future claimed economic loss from any collateral source such as insurance, social security, worker's compensation or employee benefit programs.

46. Defendant hereby gives notice to the extent the sophisticated purchaser doctrine is applicable to any of the allegations contained in the Complaint, it intends to rely upon same in defense of this action.

47. The claims asserted in the Complaint are barred, in whole or in part, because plaintiff would have taken the product even if the product labeling contained the information plaintiff contends should have been provided.

48. The claims asserted in the Complaint are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Mirapex, was not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

49. Defendant denies that Mirapex created any liability under the Alabama Extended Manufacturer's Liability Doctrine.

50. Plaintiff's claims based on negligence are subsumed by the Alabama Extended Manufacturer's Liability Doctrine.

51. With respect to each and every purported cause of action, the acts of Defendant were at all times done in good faith and without malice.

52. Defendant reserves the right to raise additional affirmative and other defenses as may be established by discovery and the evidence in this case. Defendant further reserves the right to amend its Answer and to add such

counterclaims as may become necessary after reasonable opportunity for investigation and discovery.

REQUEST FOR JURY TRIAL

Defendant requests a trial by jury on all issues triable.

PRAYER FOR RELIEF

WHEREFORE, Defendant respectfully requests that the Court:

1. Enter judgment in its favor on all claims alleged in the Complaint;
2. Award Defendant the costs, disbursements and reasonable attorneys' fees associated with these proceedings; and
3. Grant Defendant such other and further relief as the Court may deem just and proper.

This, the 21st day of July 2006.

Respectfully submitted,

s/ Kimberly Martin

Kimberly Martin (BES002)

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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2006, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

J. Greg Allen
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Counsel for Plaintiff

and I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

NONE

s/ Kimberly Bessiere Martin

Of Counsel